

IN THE CLAIMS

Claim 1. (Currently allowed). A core formulation comprising,

(a) a first layer comprising pioglitazone hydrochloride or a pharmaceutically acceptable salt thereof as active ingredient,

(b) a core, at least a portion of which is enclosed by said first layer, comprising a biguanide as active ingredient.

Claim 2. (Currently allowed). The formulation as defined in claim 1 wherein said biguanide is metformin.

Claim 3. (Currently allowed). The formulation as defined in claim 2 wherein said pioglitazone hydrochloride is present in an amount ranging from 1 mg to 45 mg and, said metformin is present in an amount ranging from 10 mg to 4000 mg.

Claim 4. (Currently allowed). The formulation as defined in claim 2 which further comprises a biodegradable shell having a predetermined rate of degradation covering at least a portion of said first layer to provide a predetermined delay in the time period of release of at least said pioglitazone hydrochloride.

Claim 5. (Currently allowed). The formulation as defined in claim 2, wherein said pioglitazone hydrochloride and/or said metformin are present as biodegradable microspheres having a biodegradable shell coating and where said shell coating has a predetermined rate of degradation.

Claim 6. (Currently allowed). A method of administering pioglitazone hydrochloride and metformin to a mammal, which comprises treating the mammal with the formulation defined in claim 2.

Claim 7. (Currently allowed). A method for producing a controlled release formulation, which comprises:

- (a) producing a hollow outer shell comprising a biodegradable material having a predetermined rate of degradation to provide a predetermined delay in the time period of release of the contents destined to be enclosed by said shell;
- (b) inserting a core comprising metformin and having an outer layer comprising pioglitazone hydrochloride partially enclosing said core, into said hollow outer shell; and
- (c) sealing said core within said hollow outer shell.

Claim 8. (Currently allowed). A method of producing a combined formulation of pioglitazone hydrochloride and metformin, which comprises:

- (a) forming a core of the metformin; and
- (b) depositing a layer of pioglitazone hydrochloride on at least a portion of a surface of said core.

Claim 9. (Currently allowed). A method of treating diabetes mellitus in a patient in need thereof, which comprises administering to the patient the formulation of claim 1 wherein said active ingredients are each present in an effective amount.

Please cancel claim 10.

Claim 10. (Currently canceled). A pharmaceutical composition in a single integral unit consisting essentially of an effective amount of pioglitazone hydrochloride combined with an effective amount of metformin.

Please cancel claim 11.

Claim 11. (Currently canceled). A method of treating diabetes mellitus in a patient in need thereof, which comprises, administering to the patient the integral composition of claim 10.

Claim 12. (Currently allowed). A pharmaceutical composition in a single integral unit consisting essentially of an effective amount of pioglitazone hydrochloride combined with an effective amount of phenformin.

Claim 13. (Currently allowed). A pharmaceutical composition in a single integral unit consisting essentially of an effective amount of pioglitazone hydrochloride combined with an effective amount of buformin.

Claim 14. (Currently allowed). A method of treating diabetes mellitus in a patient in need thereof, which comprises, administering to the patient the integral composition of claim 12.

Claim 15. (Currently allowed). A method of treating diabetes mellitus in a patient in need thereof, which comprises, administering to the patient the integral composition of claim 13.

Claim 16. (Currently allowed). A method of treating diabetes mellitus in a patient in need thereof, which comprises, administering to the patient the composition of claim 1 wherein the biguanide is phenformin.

Claim 17. (Currently allowed). A method of treating diabetes mellitus in a patient in need thereof, which comprises, administering to the patient the composition of claim 1 wherein the biguanide is buformin.